

Remarks:

Summary of Amendments Made

While the applicants believe that the pending claims prior to this amendment were allowable, in order to simplify issues for any potential appeal, the focus of the claims have been narrowed to the method of making claims (claims 11-24) and the composite material claims have been redrafted to include product by process language (claims 2-10 and 29-41).

Although it is believed that the language was clear to those of ordinary skill in the art, claim 11 has been amended to indicate that the 0.01 to 2 micron range is a range distribution in order to help the Examiner understand the principles behind the present invention and the teachings of the prior art.

Claim 28 has been cancelled. Claims 2-27 and 29-41 are now pending. It is believed that no new matter has been added.

Applicants' reserve the right to pursue the broader composite material claims via a divisional application.

Regarding the 35 U.S.C. 103(a) rejection:

Claims 2-37 were rejected as unpatentable over Tsuei et al. (U.S. Patent 5,589,194 - "Tsuei") in view of Carr et al. (U.S. Patent 5,183,690 - "Carr") and Lee et al. (EP 0 480 729 A1 - note this patent is equivalent to U.S. Patent 5,362,424 and 5,508,041 which share the same Korean priority - "Lee").

With the new limitations to the claims, it is important to emphasize again that the Tsuei and Carr references do not teach the mixing of a hydrophobic active ingredient in an oil-in-water emulsion with a matrix premix comprising a thermoplastic hydrophilic polymer as in the method defined in amended claim 11 above. In addition, Tsuei and Carr are silent as to inclusion sizes. Given the nature of Tsuei and Carr's invention, the high shear forces of their compositions would preclude inclusions having a size of 0.01 to 2 microns.

With regard to Lee, this teaching simply freeze dries any oil-in-water emulsion formed and lacks the "matrix premix comprising a thermoplastic hydrophilic polymer"

limitation of claim 11. Moreover, even if one were to take Lee's teaching of oil droplet size distribution to be equivalent to a teaching about inclusion size, this still would fail to teach the applicants 0.01 to 2 micron range distribution, i.e. formation of droplet with such small sizes are not subject to one uniform size (e.g. all droplets being 1 micron in size) but can only be represented by a distribution of sizes from smallest to largest with the majority of droplets being in the median of the range.

As such, Lee at best teaches a range of 1-5 microns, i.e. *Lee's invention has droplet sizes which exceed the largest possible size of the applicants' inclusion.*

The remainder of the applicants' position from 19 April 2004 is essentially the same and these arguments are reproduced below for the Examiner's convenience.

Determinations of obviousness first requires that each and every element of the applicants' claimed invention be taught and secondly that if more than one reference is being used to support a holding of obviousness that there be some teaching, suggestion or motivation when viewing the applicants' invention and the prior art references as a whole to combine the references. The references of record fail to establish even the first prong of the test. However, even if another reference were to be added to references cited, there is not teaching or directed to combine the isolated elements by which one of ordinary skill in the art would have arrived at the applicants' claimed invention without having the applicants' claims to act as a blueprint. For these reasons, it is believed that the claims are unobvious over the cited references and that this rejection may be rescinded.

Reprint of arguments from amendment faxed on 19 April 2004

The Tsuei and Carr patents were also used by the Examiner in her rejection of 9 April 2003 (Paper No. 17) although now the Tsuei reference is now the primary reference. However, switching the status of the reference does not change the fundamental weaknesses of the Tsuei and Carr in combination (which was addressed in the applicants' response of 7 July 2003) which the Lee reference does not remedy.

As stated by the Examiner, Tsuei fails to teach the size of the microcapsules and fails to teach starch matrix as recited in the applicants' claims. The Examiner also acknowledges that Carr also fails to teach the size of the microcapsules of the applicants' claims. As stated in applicants' 7 July 2003 response, Carr teaches the use of starch

granules to form encapsulations on the size of 400 - 1500 microns (compared to applicants' inclusion size range of 0.01 - 2 micron) and as such even if there was a specific teaching, suggestion or motivation to combine Tsuei with Carr, this would only lead to a composition with encapsulation sizes far in excess of the applicants claimed size range.

It also noted that both the Tsuei and Carr references disclose forming their respective compositions by using conventional extrusion techniques and do not form oil-in-water emulsions before extrusion/mixing with the matrix material. The high shear forces associated with these conventional techniques do not allow for the formation of inclusion sizes.

Lee does not remedy the deficiencies of the Tsuei and Carr references for the following reasons.

First, Lee describes an oil-in-water emulsion which is their final product and is not envisioned to undergo any further processing. The 1-5 micron size range describes the oil-in-water emulsion not the size of the inclusion as in the applicants' claimed material.

Second, the 0.01-2 micron and 1-5 micron ranges are size distribution ranges and does not represent an overlap of ranges, i.e. one does not obtain a composition with inclusion or oil-droplet sizes of strict uniformity (e.g. if it were possible to obtain an all 2 micron size then there could be some basis for overlap if the Examiner could show that the oil-droplet size would necessarily form the inclusion size. However, this is not what these ranges disclose and in any event, this equivalence has not been shown by the Examiner). As such, Lee by definition teaches oil-droplet sizes which are in excess of the range claimed by the applicants.

Third, if the Examiner is asserting that there is some sort of equivalence between Carr and Lee which allows for substitution of elements, it is noted that Carr relates to the use of starch granules while Lee is directed toward the use of "polysaccharide which has metal-chelating capacity". These are vastly different types of polysaccharides and even if there was a teaching, suggestion or motivation to make such a substitution, there would

be no reasonable expectation of success for making such a substitution given the differences in physical characteristics between the two different types of polysaccharides.

Fourth, Tsuei and Carr both disclose the use of conventional extrusion techniques to obtain at best encapsulation sizes of 400-1500 microns. However, Lee uses a sonification technique to obtain their 1-5 micron size range (which still is outside the range taught by the applicants). There is no teaching, suggestion or motivation to substitute Lee's sonification technique for the techniques used by Tsuei and Carr. Even if such a combination could be asserted, it still would not approach the ranges taught by the applicants.

It appears that most of the attention has been directed toward the subject matter related to claim 2, however claims 2-37 inclusive have been rejected. It is noted that MPEP 2143.03 states that "To establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." Claims 11-24 are directed toward a method of preparing a composite material which is not taught by Tsuei, Carr and Lee and claims 28-37 are directed to composite materials which specifically refer to the process steps not taught by Tsuei, Carr and Lee.

Given all the differences between the applicants' invention and the cited references, the applicants' believe that one of ordinary skill in the art having the above references before them but without the benefit of the applicants' claims to serve as a guide would allow the skilled artisan to arrive at the applicants' claimed invention.

Claims 38-41 were rejected as being obvious over Tsuei et al. in view of Carr et al. and Lee et al. as stated above, further in view of Bilbrey (U.S. Patent 5,290,547).

Should the rejection of claims 2-37 be withdrawn, it is believed that the rejections of claims 38-41 should also be withdrawn. However, should the rejection be maintained, the applicants hold that the "as a whole" consideration requirement for establishing obviousness does not allow for Bilbrey's teaching of the use of fragrance oils to be used in isolation. Bilbrey, like Lee, teaches oil-in-water emulsion but lacks a teaching for inclusions. Bilbrey also teaches droplet sizes which are well in excess of that taught by applicants.

It is well known that "virtually all [inventions] are combinations of old elements...Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat patentability of the claimed invention. Such an approach would be 'an illogical and inappropriate process by which to determine patentability.'" Sensotronics, Inc. v. Acrosonic Corp., 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996)." Rouffet, 149 F.3d at 1357, 47 USPQ2d 1457.

Reconsideration of the presently amended claims, and the propriety of the outstanding grounds of rejection is requested. As a next communication a *Notice of Allowance* is respectfully requested.

Conditional Petition for Extension of Time:

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Assistant Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

Authorization to Charge USPTO Deposit Account:

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

The undersigned points out that this response, and the accompanying RCE are being filed on the first business day following the extended response due date.

Applicants believe that this application, as presently amended, is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully Submitted;

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27 December 2004

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Agata Glinska
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27 December 2004
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